

Stepan

Stepan Company

Northfield, Illinois 60093
Telephone 847 446 7500



December 18, 2003

Honorable Michael Leavitt, Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

201-14936

Attn: Chemical Right-to-Know

Dear Administrator Leavitt:

Stepan Company is pleased to submit the proposed test plan along with the robust summaries for the chemical, Sodium Lauryl Sulfoacetate (Acetic Acid, sulfo-, 1-dodecyl ester sodium salt), CAS# 1847-58-1. Stepan Company understands there will be a 120-day review period for the test plan and that all comments generated by or provided to EPA will be forwarded to Stepan Company for consideration.

Lela Jovanovich, Ph.D. is our contact for the HPVC Program and can be reached at (847) 501-2272 or ljovanovich@stepan.com.

This submission is also being sent electronically to the following e-mail addresses:

Oppt.ncic@epa.gov
Chem.rtk@epa.gov

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Arno Driedger, Ph.D.
Sr. Director, Product Safety and Compliance

Enclosures: Assessment Report and Test Plan, Robust summaries on CAS# 1847-58-1

cc: O. Hernandez, EPA
W. Penberthy, EPA



201-14936A

**HPV Assessment Report and Test Plan for
Sodium Lauryl Sulfoacetate (Acetic Acid, sulfo-,1-dodecyl
ester sodium salt) CAS 1847-58-1**

Authors:

H.M. Barentsen Ph.D.
W.M.L.G. Gubbels-van Hal M.Sc.

18 December 2003

Prepared for STEPAN Company, Northfield, IL
by NOTOX Safety and Environmental Research BV
for submission under the US-HPV Challenge Program

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1. Introduction

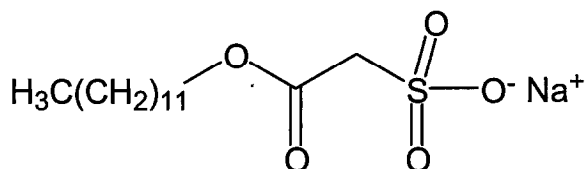
Under agreement with Stepan Company, NOTOX Safety and Environmental Research B.V. conducted an evaluation and assessment of the detergent sodium lauryl sulfoacetate (CAS 1847-58-1; commercial name: Lathanol LAL), classified as a high production volume (HPV) chemical according to criteria established by the US-EPA, i.e., >1,000,000 pounds manufactured or imported into the USA annually. Stepan Company has voluntarily agreed to complete a hazard characterization of this substance following US EPA guidance and according to the SIDS data requirements.

Sodium lauryl sulfoacetate

CAS No. 1847-58-1

Formula: $C_{14}H_{27}O_5SNa$

Molecular weight: 330



US EPA has identified 2800 HPV chemicals to be evaluated in the HPV Challenge Program. Sodium lauryl sulfoacetate, which is under evaluation in the present document, is listed as an HPV chemical. Sodium lauryl sulfoacetate is used as a cosmetic ingredient in personal care products. The commercial product Lathanol LAL Powder contains 64-85% active ingredient. The remaining components are sodium sulfate and sodium chloride. NOTOX has assisted Stepan Company to determine the suitability of the available data on sodium lauryl sulfoacetate to fulfill a screening level hazard characterization.

For the development of screening level health and environmental assessment information, NOTOX followed a step-wise approach incorporating the following elements:

1. a comprehensive literature search and retrieval of HPV data using the complementary CIS (Chemical Information Systems) and EU (European Union) data sources.
2. the application of computer models (SAR's) for estimating physicochemical and ecotoxicological properties of the candidate HPV substance.
3. the reviewing of studies and preparation of robust summaries
4. determination of the suitability of studies for meeting the SIDS data requirements and construction of a SIDS data matrix and recommendations for the draft testing plan.

The following is a summary of the studies available, an identification of data-gaps and recommended test plan.

2. Evaluation of SIDS Endpoints

An evaluation of data available on SIDS endpoints for sodium lauryl sulfoacetate is presented as follows. The robust summaries of the studies/reports evaluated (including skin/eye irritation) are contained in Appendix A.

2.1. Physicochemical Data

Data on all physicochemical endpoints are available and adequate for the purposes of the HPV challenge. The EPIWIN calculations performed (results in Appendix B) have their restrictions due to the fact that the salt is calculated with a covalent bond between the sodium ion and the sulfonate ion. This is considered acceptable. EPIWIN is expected to underestimate the water solubility and, therefore, overestimate the octanol-water partition coefficient. The physical form of sodium lauryl sulfoacetate is that of a powder or flake which dissolves in water. The water solubility value from the literature and the model estimate differ significantly. This is attributable to the fact that the observed solubility in the literature is probably a micellar solution and not a true solution, while the EPIWIN does not account for the formation of micellar solutions. The water solubility from the literature is taken as the key end point, because it will resemble the actual behavior of the substance when introduced in water. This was confirmed by the aquatic toxicity tests conducted at concentrations up to 100 mg/L.

Based on these considerations and values mentioned in Table 1, it is concluded that all SIDS endpoints have been adequately investigated and no further testing is recommended.

Table 1. Physicochemical Properties

Sodium lauryl sulfoacetate CAS 1847-58-1				
	Value	Comment	KI	Ref
Melting point (°C)	271	calculated	2	18
Boiling point (°C)	425	calculated	2	18
Relative density	0.55	review	2	9
Vapor pressure (hPa)	3.0E-14	calculated	2	18
Partition coefficient	2.66	calculated	2	18
Water Solubility (mg/L) at 25°C	10,000	review	2	9
	3.83	calculated	2	18
Dissociation constant	-0.5	calculated	1	10

KI = Klimisch criteria

Ref = Reference number

2.2. Environmental Fate

Table 2 presents a summary of available data. Data on all SIDS endpoints are available and adequate. The photodegradation in air represented by the Atmospheric Oxidation Potential or AOP model was calculated by EPIWIN to be 7.9 hours. Sodium lauryl sulfoacetate is reported as stable in water in a pH range of 5.0 to 8.5 (9). Calculation of the environmental distribution (Fugacity) at Mackay level III with discharge of the substance into water, showed that > 99% of the substance will stay in the water and that a small percentage goes to sediment.

In a biodegradation study following the OECD 301B guideline the test substance did not meet the criteria for ready biodegradability (>60% within a 10-d period) but was shown to be biodegradable to a major extent (56% removal in 29 days). Biodegradation would be considered a pathway for the removal of this substance in the environment

Based on this evaluation and data, all endpoints for environmental fate have been sufficiently investigated and the data is considered reliable and adequate. No further testing of these properties is recommended.

Table 2. Environmental Fate Properties

Sodium lauryl sulfoacetate CAS 1847-58-1				
	Value	Comment	KI	Ref
Photodegradation (t1/2 hrs)	7.9	calculated	4	18
Hydrolysis	Stable	review	4	9
Transport between compartments (% in water/air/soil/sediment)	99.3/0/0/0.65		2	18
Ready Biodegradability	not readily biodegradable	56% in 29 days; OECD 301B	1	11

KI = Klimisch criteria

Ref = Reference number

2.3. Ecotoxicity

Table 3 presents a summary of available data. Reliable and adequate data are available on the daphnia acute toxicity and algal inhibition endpoints. Freshwater algae were the most sensitive species tested. The actual concentration/effect relationship (mg/L) measured for both daphnia and algae confirmed the values estimated by the ECOSAR model. Based on the comparable data shown in Table 3, it is expected that acute fish toxicity will also fall into a similar mg/L concentration range. Because two reliable studies with measured concentrations are available to establish acute aquatic effects and these values confirm the modelling estimates it is not considered necessary to determine acute fish toxicity.

Based on the information available, acute effects on representative aquatic organisms have been sufficiently investigated and considered adequate for the HPV challenge program. The substance is considered moderately toxic to aquatic organisms.

Table 3. Ecotoxicity

Sodium lauryl sulfoacetate CAS 1847-58-1				
	Value	Comment	KI	Ref
Fish (96 h-LC50; mg/L)	22.2	calculated (ester)	4	18
Daphnia (48 h-LC50; mg/L)	5.9	OECD 202	1	13
	65.8	calculated (ester)	4	18
Algae (72 h-EC50; mg/L)	1.9	OECD 201	1	14
EC Biomass	1.8	96 h calculated (ester)	4	18

KI = Klimisch criteria

Ref = Reference number

2.4. Mammalian Toxicity

The human health effects data for SIDS endpoints are presented in Table 4. An acute oral LD50 value in the rat of > 2000 mg/kg body weight and an acute dermal LD50 value in rabbit of greater than 2000 mg/kg body weight are available. In view of its use (cosmetic) the dermal route is considered to be the most appropriate for this product. Repeated dose (28-day and 90-day) toxicity studies reported a NOAEL of 200 mg/kg/day and a NOAEL of 75 mg/kg/day, respectively. In both the Ames test and chromosomal aberration study the substance was shown not to be genotoxic with or without metabolic activation.

For the non-SIDS endpoints skin and eye irritation studies following the OECD guidelines showed that sodium lauryl sulfoacetate is moderately irritating to skin and eye. In the Journal of the American College of Toxicology (Ref 9) Cosmetic Ingredient Review (CIR) the Expert Panel concluded that sodium lauryl sulfoacetate is safe as a cosmetic ingredient in the present practices of use and concentrations.

Based on the present evaluation, all human health endpoints are adequately described with the exception of reproduction/developmental toxicity.

Table 4. Mammalian Toxicity

Sodium lauryl sulfoacetate CAS 1847-58-1				
	Value	Comment	KI	Ref
<i>Acute Toxicity</i>				
Acute Oral (LD50; mg/kg bw)	>2000	limit test ; OECD 401	1	1
Acute Dermal (LD50; mg/kg bw)	>2000	limit test ; OECD 402	1	2
Acute inhalation (LC50; mg/m ³)	-			
<i>Genetic Toxicity</i>				
Ames test	negative	with and without metab. activity; single experiments	2	6-8
Chromosomal aberration	negative	OECD 473	1	12
<i>Subchronic/Reproduction</i>				
28 day (NOAEL) (LOAEL)	200 800	limited examinations	2	4
90 day (NOAEL) (LOAEL)	75 250		1	5
Reproduction toxicity	-			
Developmental toxicity	-			

KI = Klimisch criteria

Ref = Reference number

3. SIDS Data Matrix

Sodium lauryl sulfoacetate CAS 1847-58-1				
	Value	Comment	KI	Ref
Physicochemical data				
Melting point (°C)	271		2	18
Boiling point (°C)	425		2	18
Relative density	0.55		2	9
Vapor pressure (hPa)	3 .0E-14		2	18
Partition coefficient	2.66		2	18
Water Solubility (mg/L) at 25°C	10,000		2	9
	3.83		2	18
Dissociation constant	-0.5	calculated	1	10
Environmental fate				
Photodegradation (t1/2 hrs)	7.9		4	18
Hydrolysis	Stable	review	4	9
Transport between compartments (% in water/air/soil/sediment)	99.3/0/0/0.65		2	18
Ready Biodegradability	not readily biodegradable	56% in 29 days; OECD 301B	1	11
Ecotoxicity				
Fish (96 h-LC50; mg/L)	22.2	calculated (ester)	4	18
Daphnia (48 h-LC50; mg/L)	5.9	OECD 202	1	13
	65.8	calculated (ester)	4	18
Algae (72 h-EC50; mg/L)	1.9	EC biomass; OECD 201	1	14
	1.8	96 h calculated (ester)	4	18
Mammalian toxicity				
Acute Toxicity				
Acute Oral (LD50; mg/kg)	>2000	limit test; OECD 401	1	1
Acute Dermal (LD50; mg/kg)	>2000	limit test; OECD 402	1	2
Acute inhalation (LC50; mg/m ³)	-			
Genetic Toxicity				
Ames test	negative	with and without metab. activity; single experiments	2	6-8
Chromosomal aberration	negative	OECD 473	1	12
Subchronic/Reproduction				
28 day (NOAEL)	200	limited examinations	2	4
90 day (NOAEL)	75		1	5
Reproduction toxicity	NA			
Developmental toxicity	NA			

NA – data not available

4. Data Availability and Testing Plan

The availability of data is depicted in the following table. The study that should be performed to fill a data gap has been indicated.

Table 6. Testing Plan

	Sodium lauryl sulfoacetate CAS 1847-58-1
Physico-chemical	
Melting point	+
Boiling point	+
Density	+
Vapor Pressure	+
Partition Coefficient	+
Water Solubility	+
Environmental Fate	
Photodegradation	+
Hydrolysis	+
Transport between compartments	+
Biodegradability	+
Ecotoxicity*	
96-h LC50 Fish	+
48-h EC50 Daphnia	+
72-h EC50 Algal Inhibition	+
Mammalian toxicity	
Acute	+
Repeated dose	+
Genetic Toxicity	+
Reproduction/developmental	OECD421

+ = data available and adequate

OECD = test to be performed

Conclusion

For the purpose of the HPV Challenge program adequate and reliable data are available on the physicochemical properties, environmental fate and ecotoxicity of sodium lauryl sulfoacetate. For mammalian toxicity endpoints, reliable and adequate data are also available for acute toxicity, genetic toxicity and repeated dose toxicity. Reproduction and developmental toxicity is not known. Therefore, a reproduction/developmental toxicity screening test following OECD Guideline 421 will be conducted to complete the hazard characterization of this substance.

5. References

	Author	Title	Source/performing laboratory	Year
1.	Kukulinski, M.	Acute oral study (TM study 97-119-3A)	Tox Monitor Laboratories	1997
2.	Kukulinski, M.	Acute dermal toxicity study (TM study 97-119-4)	Tox Monitor Laboratories	1997
3.	Marks, K.H.	Determination of ready biodegradability closed bottle test (Weston study 91-001)	Roy F. Weston, Fate and Effect Laboratory	1992
4.	Hill, R	28 Day oral range finding study in the rat toxicol report ref. Sus/1/c	Toxicol Laboratories Ltd	1985
5.	Hill, R	90 Day oral toxicity study in the rat 910-74	Toxicol Laboratories Ltd	1986
6.	Anonymous	No title; labelled 2-18-5	Litton Bionetics	1978
7.	Anonymous	Mutagenicity evaluation of 2300-00, lot 23N056 in the Ames Salmonella/microsome plate test.	Litton Bionetics	1978
8.	Anonymous	Mutagenicity evaluation of 3000-00, lot 30M366 in the Ames Salmonella/microsome plate test.	Litton Bionetics	1978
9.	Anonymous	Final report on the safety assessment of sodium lauryl sulfoacetate.	J. Am. Coll. Toxicol. 6(3), 261-277	1987
10.	Brekelmans, M.J.C.	Statement on the determination of the dissociation constant(s) of Lathanol LAL powder in water.	NOTOX BV	2003
11.	Desmares-Koopmans, M.J.E.	Determination of 'ready' biodegradability: carbon dioxide (CO ₂) evolution test (modified Sturm test) with Lathanol LAL powder.	NOTOX BV	2003
12.	Buskens, C.A.F.	Evaluation of the ability of Lathanol LAL powder to induce chromosome aberrations in cultured peripheral human lymphocytes.	NOTOX BV	2003
13.	Bouwman, L.M.	Acute toxicity study in Daphnia magna with Lathanol LAL powder (semi-static).	NOTOX BV	2003
14.	Bouwman, L.M.	Fresh water algal growth inhibition test with Lathanol LAL powder.	NOTOX BV	2003
15.	Kukulinski, M.	OECD guideline 404 primary dermal irritation/corrosion study (TM 97-119-2)	Tox Monitor Laboratories, Inc.	1997
16.	Bankhead, R.R.	DOT Test for corrosivity.	Rosner Hixson Laboratories	1977
17.	Kukulinski, M.	OECD guideline 405 acute eye irritation/corrosion study (TM 97-119-1).	Tox Monitor Laboratories, Inc.	1997
18.		EPISUITE v3.10 (April 2001).		2001

Appendix A

Available Measured Data

This appendix contains the robust summaries of the available data. Reference 9 was not summarised, because this reference consisted of a review containing summaries only.

The reports have been evaluated and assessed according to the Klimisch criteria (Klimisch et al., 1997). The following criteria can be distinguished, based on reliability, relevance and adequacy of the data:

- 1 = Reliable without restrictions,
- 2 = Reliable with restrictions,
- 3 = Not reliable,
- 4 = Not adequate.

List of Abbreviations

a	Absolute to body weight
-	Absent
+	Present
a.i.	Active ingredient
BOD	Biochemical Oxygen Demand
BOD ₅	Biochemical Oxygen Demand on day 5
BUN	Blood Urea Nitrogen
COD	Chemical Oxygen Demand
d	Decrease
dc	Decrease (significant)
DOC	Dissolved Organic Carbon
F	Female
i	Increase
ic	Increase (significant)
M	Male
r	Relative to body weight
TS	Test Substance
WBC	White Blood Cells
x	yes

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Physicochemical Properties

Title	Statement on the determination of the dissociation constant(s) of Lathanol LAL powder in water.
Date of report	June 13, 2003.
GLP	Yes.
Reference	10.
Test substance	CAS 1847-58-1, Lathanol LAL powder, purity 74.26%.
Guideline	OECD 112
Remarks	For the sulphonate group of Lathanol LAL powder a pK_a of -0.51 was calculated with Pkalc version 5.0. Since this value is not within the range 2-11 the dissociation constant could not be determined experimentally.
Conclusions	pK_a = -0.5.
Rev. note	-
Klimisch criterium	1

Title	Final report on the safety assessment of sodium lauryl sulfoacetate.
Date of report	1987.
GLP	No.
Reference	9.
Test substance	CAS: 1847-58-1, Sodium Lauryl Sulfoacetate.
Guideline	Not indicated.
Remarks	Specific gravity = 0.55. Water solubility = 10, 000 mg/L at 25 °C. The pH of a 0.25% solution is 6.9-7.1.
Rev. note	-
Klimisch criterium	2

Title	EPISUITE v.3.10
Date of report	-
GLP	Not applicable.
Reference	18.
Test substance	CAS 1847-58-1, acetic acid, sulfo-, 1-dodecyl ester, sodium salt.
Guideline	Not applicable.
Remarks	Melting point: 271 °C. Boiling point: 425 °C. Vapor pressure: 3.0E-14 hPa at 25 °C. Partition coefficient o/w: 2.66. Water solubility: 3.83 mg/L at 25 °C.
Rev. note	Calculated.
Klimisch criterium	2

Environmental Fate

Title	Final report on the safety assessment of sodium lauryl sulfoacetate.
Date of report	1987.
GLP	No.
Reference	9.
Test	CAS: 1847-58-1, Sodium Lauryl Sulfoacetate.

substance
Guideline Not indicated.
Remarks The test substance is stable in weakly acidic and weakly alkaline solutions in a pH range of 5.0-8.5.
Rev. note -
Klimisch 4
criterion

Title EPISUITE v.3.10
Date of report -
GLP Not applicable.
Reference 18.
Test substance CAS 1847-58-1, acetic acid, sulfo-, 1-dodecyl ester, sodium salt.

Guideline Not applicable.
Remarks **Photodegradation (calculated):**
 AOP Program (v1.90) Results:

=====
 SMILES : S(=O)(=O)(O[Na])CC(=O)OCCCCCCCCCCCCC
 CHEM : Acetic acid, sulfo-, 1-dodecyl ester, sodium salt
 MOL FOR: C14 H27 O5 S1 Na1
 MOL WT : 330.42

----- SUMMARY (AOP v1.90): HYDROXYL RADICALS -----

**Hydrogen Abstraction = 16.1612 E-12 cm3/molecule-sec
 Reaction with N, S and -OH = 0.0000 E-12 cm3/molecule-sec
 Addition to Triple Bonds = 0.0000 E-12 cm3/molecule-sec
 Addition to Olefinic Bonds = 0.0000 E-12 cm3/molecule-sec
 Addition to Aromatic Rings = 0.0000 E-12 cm3/molecule-sec
 Addition to Fused Rings = 0.0000 E-12 cm3/molecule-sec

OVERALL OH Rate Constant = 16.1612 E-12 cm3/molecule-sec

HALF-LIFE = 0.662 Days (12-hr day; 1.5E6 OH/cm3)

HALF-LIFE = 7.942 Hrs

..... ** Designates Estimation(s) Using ASSUMED Value(s)

----- SUMMARY (AOP v1.90): OZONE REACTION -----

***** NO OZONE REACTION ESTIMATION *****
 (ONLY Olefins and Acetylenes are Estimated)

Distribution (calculated):**Level III Fugacity Model (Full-Output):**

=====

Chem Name : Acetic acid, sulfo-, 1-dodecyl ester, sodium salt
 Molecular Wt: 330.42
 Henry's LC : 6.79e-010 atm-m3/mole (Henrywin program)
 Vapor Press : 3.02e-014 mm Hg (Mppbpwin program)
 Liquid VP : 8.26e-012 mm Hg (super-cooled)
 Melting Pt : 271 deg C (Mppbpwin program)
 Log Kow : 2.66 (Kowwin program)
 Soil Koc : 187 (calc by model)

	Mass Amount (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	8.25e-006	15.9	0
Water	99.3	360	1000
Soil	0.000113	360	0
Sediment	0.654	1.44e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	1.92e-022	0.00124	0.000284	0.000124	2.84e-005
Water	3.51e-015	657	341	65.7	34.1
Soil	9.22e-021	0.000746	0	7.46e-005	0
Sediment	2.1e-015	1.08	0.045	0.108	0.0045

Persistence Time: 344 hr
 Reaction Time: 522 hr
 Advection Time: 1.01e+003 hr
 Percent Reacted: 65.8
 Percent Advected: 34.2

Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):

Air: 15.88
 Water: 360
 Soil: 360
 Sediment: 1440
 Biowin estimate: 3.149 (weeks)

Advection Times (hr):

Air: 100
 Water: 1000
 Sediment: 5e+004

Conclusion Indirect photolysis in air results in a half-life of 7.9 hours for the test substance.
 Discharge into water results in the following distribution:
 water/air/soil/sediment = 99.3/0/0/0.65%

Rev. note -
Klimisch 4
criterion

Title Determination of 'ready' biodegradability: carbon dioxide (CO₂) evolution test (modified Sturm test) with Lathanol LAL powder.
Date of report June 17, 2003.
GLP Yes.
Reference 11.
Test substance CAS 1847-58-1, Lathanol LAL powder, purity 74.26%.
Guideline OECD 301B

Procedure

A stock solution of 1.00 g/L Lathanol LAL powder was prepared using ultrasonication. The stock was a light glassy solution. Since calculation of the theoretical TOC value was not possible, the TOC concentration of the stock was measured and determined to be 361.5 mg/L. The theoretical CO₂ production based on the TOC was calculated to be 1.33 mg CO₂/ml stock solution.

Duplicate test mixtures were incubated with activated sludge in 2 L brown-coloured glass bottles with three serial CO₂-absorbers ((Ba(OH)₂) each and at a temperature of 21.4-23.5 °C for 28 days. Test mixtures contained test substance (33 mg/L) and filtrate of non-adapted inoculum (10 ml/L mineral medium) in mineral medium as prescribed in OECD 301B. The following controls were included:

- Inoculum blank: control without test substance but with inoculum (2 flasks).
- Positive control: reference substance (sodium acetate; 40 mg/L) with inoculum (1 flask).
- Toxicity control: Lathanol LAL powder (33 mg/L), sodium acetate (40 mg/L) and inoculum (1 flask).

Evolution of carbon dioxide was determined on day 0, 2, 5, 7, 9, 14, 14, 19, 23, 27 and 29 by titrating the remaining barium hydroxide with 0.05 M hydrogen chloride.

Results

Day	% degradation			
	TS with inoculum			Sodium acetate
	A (33 mg/L)	B (33 mg/L)	Mean	
2	0	0	0	6
5	5	20	12	40
9	18	33	26	65
19	42	51	47	85
23	45	56	50	88
29	51	62	56	94

Conclusions

Lathanol LAL powder is not readily biodegradable under the above test conditions.

Rev. note

1. The test substance was not inhibitory on microbial activity.

Klimisch

1

criterion**Title**

Determination of ready biodegradability closed bottle test (Weston study 91-001),.

Date of report

October 20, 1992.

GLP

Yes.

Reference

3.

Test

Lathanol LAL slurry (a.i. sodium lauryl sulfoacetate (CAS 1847-58-1)), purity 15.1% (carbon content 7.8% (w/w) in this formulation)

substance**Guideline**

OECD 301 D

Procedure

Duplicate test mixtures (7 flasks) were incubated in 300 mL glass BOD bottles at 20 +/- 0.2 °C for 28 days. Test mixtures (in completely filled flasks) contained test substance (2 mg/L or 5 mg/L), filtrate of (non-adapted) effluent from duplicate semi-continuous activated sludge units (40 µL) and mineral medium essentially as prescribed in OECD 301 D. The following controls were included:

- Inoculum blank: control without test substance but with inoculum (7 flasks).
- Positive control: reference substance (sodium benzoate; 2 mg/L) with inoculum (7 flasks).
- Complete blank: control without test substance and without inoculum (7 flasks).

Dissolved oxygen was determined on day 0, 5, 15 and 28. Degradation was calculated as BOD/COD. On day 0 single flasks were analysed, on the other time points duplicate flasks were analysed. Only BOD₅ was determined for glucose/glutamic acid control.

Results

Day	% degradation ¹		
	TS with inoculum ¹		Sodium benzoate ¹
	2 mg/L	5 mg/L	
5	31.6	30.9	68.4
15	43.2	34.9	74.7
28	65.9	>38.4 ²	>100 ²

¹ mean of two replicates

² dissolved oxygen value was below detection limit, therefore ">" value was reported

Conclusions Some components of the formulation are biodegradable.
Rev. note 1. Composition was not specified. Oxygen consumption observed may (partly) represent biodegradation of additives.
 2. No abiotic control was included. Since the report does not indicate that the test was performed in the dark, photodegradation cannot be excluded.
Klimisch criterium 3 Degradation may be related to other components (note 1).

Aquatic Toxicity

Title Acute toxicity study in *Daphnia magna* with Lathanol LAL powder (semi-static).
Date of report 18 December, 2003.
GLP Yes.
Reference 13.
Test substance CAS 1847-58-1, Lathanol LAL powder, purity 74.26%.
Test method OECD 202.
Test system **Species** *Daphnia magna*, <24 h old.
No. of daphnids 5/replicate, 4 replicates/treatment.
Concentrations Nominal: 1.0, 2.2, 4.6, 10, 22 and 46 mg/L (no vehicle; prepared from stock solution 46 mg/L); blank control.
Test conditions Semi-static without aeration; in 100 mL glass beakers containing 80 mL of medium (hardness 201 mg/L as CaCO₃), 16 h light, no feeding.
Exposure time 48 hours.
Analyses LC-MS. Samples taken at 0 and 24 h from freshly prepared solutions, and at 24 and 48 h from 24 h-old solutions.
Phys. meas. pH and dissolved oxygen: at 0, 24 and 48 h for all concentrations and control; pH = 7.8-7.9 and dissolved oxygen = 8.8-9.3 mg/L.
Temperature: continuously; 20-21 °C
 Physical parameters remained within the required ranges during the test.
Observations Immobility at 24 and 48 h.
Stat. method Probit analysis.
Results **Ref. product** A test with the reference substance K₂Cr₂O₇ was performed in August 2003. The 48 h-EC₅₀ of K₂Cr₂O₇ was 0.75 mg/L.
Analysis Measured concentrations were within 82-99% of the nominal concentrations.

Biological results

Parameter	Time [h]	Nominal concentration [mg/L]					
		1.0	2.2	4.6	10	22	46
Immobility [%]	24	0	0	0	40	85	100
	48	0	0	0	80	100	100

Conclusions 48-h EC₅₀ = 7.9 mg/L (equivalent to 5.9 mg/L based on a.i.).
Rev. note 1. The two highest test concentrations still contained a very thin layer of foam. All final test solutions were clear and colourless.
Klimisch criterium 1

Title Fresh water algal growth inhibition test with Lathanol LAL powder.
Date of report 18 December, 2003.
GLP Yes.
Reference 14.
Test substance CAS 1847-58-1, Lathanol LAL powder, purity 74.26%.
Guideline OECD 201.
Test system **Species** *Selenastrum capricornutum*, strain: NIVA CHL 1.
Initial cell conc. 1*10⁴ cells/mL.
No. of replicates 3 per treatment; 6 for blank control; 1 replicate of each test concentration without algae; 1 extra replicate of each test concentration and blank control for sampling purposes.
Concentrations Nominal 1.0, 2.2, 4.6, 10, 22, 46 and 100 mg/L, blank control.

Test conditions 72-h static test in 100 ml glass vessels containing medium (in accordance with OECD 201) with continuous illumination (ca. 4900-6400 lux).

Analysis LC-MS. Samples were taken at 0, 24 and 72 h.

Phys. meas. pH: at 0 and 72 h; 7.8-9.0; in the blank control an increase of 1.5 was observed which correlated with a high rate of algal growth (7.9-9.4)

Observations Temperature: continuously; 23.0 – 24.1°C.
Cell density at 0, 24, 48 and 72 h by spectrophotometry or microscope using a counting chamber.

Stat. method ANOVA, Bonferroni t-test, Tukey test and Williams' test.

Results For biological data see table below. Growth factor control = 95.

Biological results

Parameter	Time [h]	Measured concentration [mg/L]							
		0	0.36	0.86	1.7	3.4	7.2	14	31
Mean cell density [$\times 10^4$ cells/ml]	0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
	24	3.1	2.8	2.6	2.1	1.4	1.3	2.2	1.3
	48	24.3	20.3	19.4	15.0	8.1	1.9	2.0	1.3
	72	95.5	80.4	81.0	62.9	33.6	6.0	6.1	1.3
Inhibition [%] – AUC	72-h		16.3	17.5	36.7	67.2	94.9	93.5	99.1
Inhibition [%] – growth rate	72-h		4.0	3.7	9.2	24.2	60.7	60.4	95.9

Conclusions 72 h- E_bC_{50} = 1.9 mg/L.
72 h- E_rC_{50} = 6.8 mg/L.
NOEC_r = 0.86 mg/L.

Rev. note 1. The nominal 72 h- E_rC_{50} of potassium dichromate was 0.89 mg/L.
2. Initial test solutions were all clear and colourless. Concentrations were not stable, especially over the last 48 hours. The concentrations in the vessels without algae decreased to the same extent. This is explained by possible biodegradation, since the test solutions became turbid during exposure, which may indicate bacterial growth.

Reliability 1.

Title EPISUITE v.3.10

Date of report -

GLP Not applicable.

Reference 18.

Test substance CAS 1847-58-1, acetic acid, sulfo-, 1-dodecyl ester, sodium salt.

Guideline Not applicable.

Remarks ECOSAR Class Organism Duration End Point mg/L (ppm)

=====	=====	=====	=====	=====
Esters :	Fish	96-hr	LC50	22.180
Esters :	Daphnid	48-hr	LC50	65.836
Esters :	Green Algae	96-hr	EC50	1.809

Rev. note Calculated.

Klimisch criterium 4

Mammalian Toxicity*Acute Toxicity*

Title Acute oral toxicity study (TM study 97-119-3A).

Date of report October 31, 1997.

GLP Yes.

Reference 1.

Test substance CAS: 1847-58-1, sodium lauryl sulfoacetate, purity 64-85%; impurities 5-18% sodium sulphate and 10-18% sodium chloride.

Guideline OECD 401.
Stat. method Not applicable.
Test system **Species** Rat (Sprague-Dawley), weight males 219-223 g, weight females 200-204 g; age 6-10 weeks; source: Harlan Sprague-Dawley, Indianapolis
No. of animals 5/sex/treatment.
Dosage Single oral administration by gavage of 2000 mg/kg bw (vehicle distilled water, concentration 33% w/v); no controls; feeding *ad libitum* (food was withheld overnight prior to dosing).
Observations Mortality and clinical signs several times on day 1 and daily thereafter until day 14.
 Bodyweight at study initiation, on days 7 and 14 and at death
 Necropsy on day 14.

Results

Effect/Dose [mg/kg bw]		2000	
Sex	Day	M	F
Mortality (day)	1-14	1 (2)	1 (2)
BW		- (animal that died)	- (animal that died)
Clinical signs ^(A)	1-14	+	+
Necropsy ^(B)	14	+	+

(A) Clinical observations included loose stool, hypoactivity and prostration (one animal) on day 1.

(B) Only in the animals that died stomach and intestines distended with gas and fluid were seen. The female also displayed a small intestine red in colour.

Conclusions Oral LD₅₀ > 2000 mg/kg bw.

Klimisch criterium 1

Title Acute dermal toxicity (TM study 97-119-4),
Date of report September 29, 1997
GLP Yes
Reference 2
Test substance CAS: 1847-58-1, Sodium Lauryl Sulfoacetate, purity 64 – 85%; impurities 5-18% sodium sulphate and 10-18% sodium chloride.
Guideline OECD 402
Stat. method Not applicable
Test system **Species** Rabbit (New Zealand White), weight 2.0-2.4 kg, age 8-12 weeks
No. of animals 5/sex/treatment.
Dosage Single administration of 2000 mg/kg bw (substance was slightly moistened before administration); area of application ca. 10% of total body surface (under occlusion); contact period of 24 hours; no controls;
Observations Mortality and clinical signs several times on day 1 and daily thereafter until day 14.
 Body weight prior to dosing , on days 7 and 14, and at death.
 Necropsy on day 14.

Results

Effect/Dose [mg/kg bw]		2000	
Sex	Day	M	F
Mortality (day)	1-14	3 (4 or 5)	1(4)
Clinical signs ^(A)	1-14	+	+
Necropsy ^(B)	14	+	-

(A) Clinical observations included erythema (until day 7-8), oedema (until day 9-11), eschar&coriaceousness (until day 11-14) and formation of scar tissue. Three males exhibited chemical burns until day 3-4 (death).

(B) Findings consisted of severe tissue damage & necrosis of the skin at the application site in all rats that died, a stomach devoid of contents in two males that died and scar tissue at the application site in some surviving animals.

Conclusions Dermal LD₅₀ > 2000 mg/kg bw.

Klimisch criterium 1

Title Final report on the safety assessment of sodium lauryl sulfoacetate.
Date of report 1987.
GLP No.
Reference 9.
Test substance Bath additive.
Guideline Not indicated.
Remarks Groups of 10 female Harlan Wistar rats (115-135 g) were given single oral doses (5-14 g bath additive/kg) of a bath additive (containing 50% sodium lauryl sulfoacetate) as a 35% aqueous solution. Leg weakness, obtunded righting reflex, ataxia, diuresis and diarrhea were observed. Most deaths occurred 4-24 h after treatment.
Conclusion LD₅₀ = 5.75 g/kg bath additive (= 0.7 g/kg sodium lauryl sulfoacetate). Recalculated by the reviewer as 5.75 x 0.5 x 0.35 = 1.0 g/kg sodium lauryl sulfoacetate.
Rev. note The information given was limited to the above mentioned. The other components of the bath additive are not known and thus the toxicity seen might be attributable to another component.
Klimisch criterium 3

Skin/eye irritation

Title OECD guideline 404 primary dermal irritation/corrosion study (TM 97-119-2).
Date of report September 29, 1997.
GLP Yes.
Reference 15.
Test substance Lathanol LAL, purity 64-85%; impurities: 5-18% sodium sulfate, 10-18% sodium chloride.
Guideline OECD 404.
Test system **Species** Rabbit (New Zealand White), weight 1850-2320 g.
No. of animals 6 males.
Dosage Application of 0.5 g test substance, moistened with distilled water, on the clipped skin under semi-occlusion for 4 hours.
Observations Skin observations at ½, 24, 48 and 72 h and at 7 and 14 days after removal of the dressing.

Results

Animal	1		2		3		4		5		6	
Time	E	O	E	O	E	O	E	O	E	O	E	O
½ h	1	0	1	1	1	2	1	2	1	2	1	2
24 h	1	0	0	0	1	1	2	1	2	1	2	2
48 h	1	0	0	0	2	0	2	0	2	0	3	1
72 h	1	0	0	0	2	0	2	0	2	0	3	1
7 days	0	0	0	0	0	0	0	0	0	0	1	0
14 days	0	0	0	0	0	0	0	0	0	0	0	0

E=erythema O=oedema
Conclusions Moderately irritating.
Klimisch criterium 1

Title DOT test for corrosivity.
Date of report May 31, 1977.
GLP No.
Reference 16.
Test substance Lathanol LAL, purity 64-85%; impurities: 5-18% sodium sulfate, 10-18% sodium chloride.
Guideline Not specified.
Test system **Species** Rabbit.
No. of animals 6 males.
Dosage Application of 0.5 ml test substance on the clipped skin under occlusion for 4 hours.
Observations Skin observations at 0, 24, and 72 after removal of the dressing.

Results

Animal	1		2		3		4		5		6	
Time	E	O	E	O	E	O	E	O	E	O	E	O
0 h	1	1	1	0	1	1	1	1	1	1	1	1
24 h	1	0	1	0	1	0	0	0	1	0	0	0
72h	0	0	0	0	0	0	0	0	0	0	0	0

E=erythema

O=oedema

Rev. note 1. The scoring used is not known to the reviewer; the appendix was not included.

Klimisch criterium 4 The information given is limited to the above mentioned.

Title Final report on the safety assessment of sodium lauryl sulfoacetate.

Date of report 1987.

GLP No.

Reference 9.

Test substance CAS: 1847-58-1, Sodium Lauryl Sulfoacetate.

Guideline Not indicated.

Remarks Undiluted sodium lauryl sulfoacetate (0.5 g) moistened with 0.9% saline was applied to the skin of 6 New Zealand rabbits for 24 hours (semi-occlusion). Test sites were scored at 30 min and 24 hours after patch removal. The mean PII was 2.7. One animal had areas of possible necrosis within the test site at 24 hours.

Rev. note The information given was limited to the above mentioned. Worst case exposure (24 h).

Klimisch criterium 4

Title Final report on the safety assessment of sodium lauryl sulfoacetate.

Date of report 1987.

GLP No.

Reference 9.

Test substance Bath additive.

Guideline Not indicated.

Remarks Undiluted bath additive (powder; 500 mg) containing 35% of sodium lauryl sulfoacetate (175 mg) and a 1% solution of the bath additive were applied to the skin of 3 rabbits for 4 days. No irritation was observed at the sites treated with the powdered bath product. All sites treated with 1% solution had slight erythema on day 2 but were normal on day 7.

Rev. note The information given was limited to the above mentioned. The other components of the bath additive are not known and thus the toxicity seen might be attributable to another component.

Klimisch criterium 3

Title Final report on the safety assessment of sodium lauryl sulfoacetate.

Date of report 1987.

GLP No.

Reference 9.

Test substance Bath additive.

Guideline Not indicated.

Remarks Undiluted bath additive (powder; 500 mg) containing 35% of sodium lauryl sulfoacetate (175 mg) and a 1% solution of the bath additive were applied to separate sites on the skin of 3 rabbits for 4 days. No irritation was observed at the sites treated with the powdered bath product. All sites treated with 1% solution had slight erythema on day 2 but were normal at day 7.

Rev. note The information given was limited to the above mentioned. The other components of the bath additive are not known and thus the toxicity seen might be attributable to another component.

Klimisch criterium 3

Title OECD guideline 405 acute eye irritation/corrosion study (TM 97-119-1).
Date of report October 2, 1997.
GLP Yes.
Reference 17.
Test substance Lathanol LAL, purity 64-85%; impurities: 5-18% sodium sulfate, 10-18% sodium chloride.
Guideline OECD 405.
Test system **Species** Rabbit (New Zealand White), weight 2010-2300 g.
No. of animals 6 females.
Dosage Instillation of 87-90 mg test substance (0.1 ml).
Observations At 1, 24, 48 and 72 h and at 7, 14 and 21 days after removal of the dressing.
 From 24 hours onwards also fluorescein and UV-light examination was used.

Results

Animal	1				2				3				4				5				6			
Time	C	I	Conj ^(A)		C	I	Conj ^(A)		C	I	Conj		C	I	Conj ^(A)		C	I	Conj ^(A)		C	I	Conj ^(A)	
			R	Ch			R	Ch			R	Ch			R	Ch			R	Ch			R	Ch
1 h	-	1	2	2	-	1	2	3	-	0	2	2	-	1	2	3	-	0	2	3	-	1	2	2
24 h	1	1	2	2	1	1	2	2	1	1	2	1	1	1	2	2	1	1	2	2	1	1	2	2
48 h	1	1	2	2	1	1	2	2	1	1	2	1	1	0	2	2	1	0	2	2	1	0	2	1
72 h	1	1	2	2	1	1	2	2	1	0	2	1	1	0	2	2	1	0	1	1	1	0	1	1
7 days	1	1	1	1	1	1	2	2	1	0	1	1	1	0	2	2	1	0	1	1	0	0	1	1
14 days	2	1	1	1	2	1	2	2	0	0	1	0	0	0	1	0	0	0	1	0	0	0	0	0
21 days	2	0	1	0	3	1	2	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0

C=corneal opacity I=Iris Conj=conjunctiva Red=redness Ch=chemosis.

(A) Severe discharge was observed.

Conclusions Moderately irritating.**Klimisch criterium** 1**Title** Final report on the safety assessment of sodium lauryl sulfoacetate.**Date of report** 1987.**GLP** No.**Reference** 9.**Test substance** Bath additive/milk.**Guideline** Not indicated.

Remarks One eye of six rabbits was treated with 0.1 ml 1% solution of bath additive containing 35% sodium lauryl sulfoacetate and observed for 4-7 days. Slight conjunctival redness was observed 1 h after treatment and had dissipated by 48 h. The cornea and iris appeared normal.

One eye of three female New Zealand rabbits was treated with a 10% aqueous solution of a milk bath containing 30% sodium lauryl sulfoacetate. All rabbits had minimal conjunctival irritation at 1 and 24 h and no irritation at 48 h.

Conclusion A 0.35% and 3% solution of sodium lauryl sulfoacetate are not irritating to the eye.

Rev. note The information given was limited to the above mentioned. The other components of the bath additive/milk bath are not known and thus the toxicity seen might be attributable to another component.

Klimisch criterium 3**Mutagenicity****Title** Mutagenicity evaluation of 2800-00, Lot 28M024 in the Ames Salmonella/ Microsome plate test.**Date of report** September 20, 1978.**GLP** No.**Reference** 6.

Test substance 2800-00, Lot 28M024, purity not indicated.
Guideline Not indicated.
Test system **Bacterial strains** TA98, TA100, TA1535, TA1537, TA1538 and D4(*Saccharomyces cerevisiae*).
Initial bacteria conc. Ca. 10^8 cells from an overnight culture.
Metabolic activation Liver S9 mix (Aroclor 1254-induced).
Test concentrations 1, 10, 100, 500 and 1000 µg /plate.
Controls Negative: solvent (DMSO).
Positive: N-methyl,N-nitro,N-nitrosoguanidine (TA1535, TA100, D4), 9-aminoacridine (TA1537), 2-nitrofluorene (TA98 and TA1538) all without S9; 2-anthramine for all strains with S9.
Test type Plate incorporation; incubation for 48 h at 37 °C. D4-yeast plates were incubated at 30 °C for 3-5 days.
No. of replicates 1.
Criteria for evaluating results The result was considered positive, if a positive dose response was observed over three concentrations.

Results

Tester strain	Test result ^(A)	
	Without activation	With activation
TA98	-	-
TA100	-	-
TA1535	-	-
TA1537	-	-
TA1538	-	-
D4	-	-

+/- : positive/negative result; positive controls gave expected responses.
 Cytotoxicity was observed at 1000 µg/plate.

Conclusion Not mutagenic.

Rev. note 1. According to handwritten text on the front page of the report, substance 2800-00, Lot 28M024 corresponds to sodium lauryl sulfoacetate, 3% in shampoo.
 2. For each test concentration only single experiments were performed.
Klimisch criterium 2 Single experiments (see note 2); non GLP.

Title Mutagenicity evaluation of 2300-00, Lot 23N056 in the Ames Salmonella/microsome plate test.

Date of report September 21, 1978.

GLP No.

Reference 7.

Test substance 2300-00, Lot 23N056, purity not indicated.

Guideline Not indicated.

Test system **Bacterial strains** TA98, TA100, TA1535, TA1537, TA1538 and D4(*Saccharomyces cerevisiae*).
Initial bacteria conc. Ca. 10^8 cells from an overnight culture.
Metabolic activation Liver S9 mix (Aroclor 1254-induced).
Test concentrations 1, 10, 100, 500 and 1000 µg /plate.
Controls Negative: solvent (water).
Positive: N-methyl,N-nitro,N-nitrosoguanidine (TA1535, TA100, D4), 9-aminoacridine (TA1537), 2-nitrofluorene (TA98 and TA1538) all without S9; 2-anthramine for all strains with S9.
Test type Plate incorporation; incubation for 48 h at 37 °C. D4-yeast plates were incubated at 30 °C for 3-5 days.
No. of replicates 1.
Criteria for evaluating results The result was considered positive, if a positive dose response was observed over three concentrations.

Results

Tester strain	Test result ^(A)	
	Without activation	With activation
TA98	-	-
TA100	-	-
TA1535	-	-
TA1537	-	-
TA1538	-	-
D4	-	-

+/- : positive/negative result; positive controls gave expected responses.

Slight cytotoxicity was observed at 1000 µg/plate.

Conclusion Not mutagenic.

Rev. note 3. According to handwritten text on the front page of the report, substance 2300-00, Lot 23N056 corresponds to sodium lauryl sulfoacetate, 23% in a cleansing bar.

4. For each test concentration only single experiments were performed. A repeat test was conducted for TA1535 and TA1537 and the result was also negative.

Klimisch criterium 2 Single experiments (see note 2); non GLP.

Title Mutagenicity evaluation of 3000-00, Lot 30M366 in the Ames Salmonella/microsome plate test.

Date of report September 13, 1978.

GLP No.

Reference 8.

Test substance 3000-00, Lot 30M366, purity not indicated.

Guideline Not indicated.

Test system **Bacterial strains** TA98, TA100, TA1535, TA1537, TA1538 and D4(Saccharomyces cerevisiae).

Initial bacteria conc. Ca. 10⁸ cells from an overnight culture.

Metabolic activation Liver S9 mix (Aroclor 1254-induced).

Test concentrations 1, 10, 100, 500 and 1000 µg /plate.

Controls Negative: solvent (water).
Positive: N-methyl,N-nitro,N-nitrosoguanidine (TA1535, TA100, D4), 9-aminoacridine (TA1537), 2-nitrofluorene (TA98 and TA1538) all without S9; 2-anthramine for all strains with S9.

Test type Plate incorporation; incubation for 48 h at 37 °C. D4-yeast plates were incubated at 30 °C for 3-5 days.

No. of replicates 1.

Criteria for evaluating results The result was considered positive, if a positive dose response was observed over three concentrations.

Results

Tester strain	Test result ^(A)	
	Without activation	With activation
TA98	-	-
TA100	-	-
TA1535	-	-
TA1537	-	-
TA1538	-	-
D4	-	-

+/- : positive/negative result; positive controls gave expected responses.

Cytotoxicity was observed at 1000 µg/plate.

Conclusion Not mutagenic.

Rev. note 5. According to handwritten text on the front page of the report, substance 3000-00, Lot 30M366 corresponds to sodium lauryl sulfoacetate, 19% in a cleansing bar.

6. For each test concentration only single experiments were performed.

Klimisch criterium 2 Single experiments (see note 2); non GLP.

Title Evaluation of the ability of Lathanol LAL powder to induce chromosome aberrations in cultured peripheral human lymphocytes.

Date of report July 22, 2003.

GLP Yes.

Reference 12.

Test substance CAS 1847-58-1, Lathanol LAL powder, purity 74.26%.

Guideline OECD 473.

Stat. method Chi-square test.

Test system **Cell line** Human lymphocytes.
Metabolic activation Rat S9 mix (Aroclor 1254-induced).
Test concentrations 50 - 500 µg/ml (based on cytotoxicity).
Controls Negative: vehicle control (DMSO).
Positive: mitomycin-C (-S9), cyclophosphamide (+S9).
Procedure -S9: 3 h exposure + 24 h fixation.
24 h exposure + 24 h fixation.
48 h exposure + 48 h fixation.
+S9: 3 h exposure + 24 h fixation.
3 h exposure + 48 h fixation.
Colchicine was added for the last 3 hours.

Results

Exposure/fixation (h)	Metabolic activation	Doses evaluated [µg/ml]	Aberrations [%]	Test result ^(A)
3/24	Without	0, 100, 300, 500	3, 7, 4, 5	-
3/24	With	0, 100, 300, 500	2, 3, 6, 7	-
3/48	With	0, 300, 400, 500, 600	0, 0, 3, 5, 9	+/-
24/24	Without	0, 100, 125, 200	2, 5, 0, 1	-
48/48	Without	0, 56, 100, 130	1, 4, 1, 5	-

(A)+/- : positive/negative result; positive controls gave expected responses.

Cytotoxicity was observed at ≥200 without metabolic activation and ≥500 µg/ml with metabolic activation.

Conclusion Not clastogenic.

Rev. note All values remained within historical control values. The statistically significant increase in the number of cells with chromosome aberrations at 600 µg/ml was ascribed to the strongly cytotoxic effect of this concentration (MI 36%).

Reliability 1.

Repeated Dose Toxicity

Title 28 day oral range finding study in the rat.

Date of report August 1985.

GLP Yes.

Reference 4.

Test substance CAS 1847-58-1 (sodium lauryl sulfoacetate), purity 73.80%; impurities: 13.09% sodium chloride, 11.39% sodium sulfate, 1.95% free oil and 0.28% water.

Guideline Not indicated.

Stat. method Student's t-test.

Test system **Species** CD rat.
Source Charles River UK.
Bodyweight Males 123-149 g g, females 114-142 g.
No. of animals 5/sex/treatment.
Dosage 0, 50, 200 and 800 mg/kg/day by gavage (dosing volume 10 ml/kg/day).
Vehicle Distilled water.
Exposure period 28 days.

Investigations **General** Clinical signs, mortality (daily), food consumption (group mean weekly), bodyweight (daily).
Clinical pathology Haematology: haematocrit, haemoglobin, erythrocyte count, mean cell volume, mean cell haemoglobin concentration and total leucocyte count.
Biochemistry: blood urea nitrogen, glucose, alkaline phosphatase, glutamate pyruvate transaminase, glutamate oxaloacetate

Necropsy transaminase and total protein.
Gross examination, macroscopy of cranial, thoracic and visceral cavities, organ weights (brain, kidneys, liver).

Analysis Concentration analysis on day 1.

Results

Dose	0 mg/kg		50 mg/kg		200 mg/kg		800 mg/kg		Dose related	
Sex	M	F	M	F	M	F	M	F	M	F
Mortality	No deaths occurred									
Clinical Signs (A)						+	+	+		
Body weight (gain)										
Food consumption						d		d		
Haematology	No changes of toxicological significance.									
Clinical chemistry	No changes of toxicological significance.									
Necropsy										
Macroscopy (B)							+			
Liver weight							i ^{a,r}			
Kidney weight								ic ^r		
Brain weight								ic ^r		

Where i=increase; d=decrease; ic=significant increase; dc=significant decrease; ^a=absolute; ^r=relative.

(A) Poor coat condition; was already present in all animals before treatment but had disappeared by day 11 except for females at 800 mg/kg. Males at 800 mg/kg and females at 200 mg/kg showed the condition again from day 22 and 15 resp. Post dose salivation in all animals at 800 mg/kg.

(B) Raised black foci on the non glandular mucosa of the stomach in one male.

Actual concentrations Concentrations as measured were 98-108% of nominal concentrations.

Conclusions NOAEL = 200 mg/kg/day and LOAEL = 800 mg/kg/day based on <10% effect on body weight.

Rev. note

1. No histological examinations were performed.
2. Only limited biochemical parameters were investigated.
3. Only a limited number of organs were weighed.

Klimisch criterium 2.

Title 90 day oral toxicity study in the rat.

Date of report March 1986.

GLP Yes.

Reference 5.

Test substance CAS 1847-58-1 (sodium lauryl sulfoacetate), purity 73.80%; impurities: 13.09% sodium chloride, 11.39% sodium sulfate, 1.95% free oil and 0.28% water.

Guideline Not indicated.

Stat. method ANOVA, Student's t-test.

Test system

Species Rat, CD (SD) BR strain.

Source Charles River UK.

Bodyweight Males 114-153 g g, females 106-135 g.

No. of animals 20/sex/treatment; satellite group of 10/sex for to provide pre-exposure clinical pathology.

Dosage 0, 75, 250 and 750 mg/k/day by gavage (dosing volume 10 ml/kg).

Vehicle Distilled water.

Exposure period 91 days.

Investigations

General Clinical signs and mortality (daily), food consumption (group mean weekly), bodyweight (daily), ophthalmoscopy (before study initiation in all animals and after 4 and 12 weeks of treatment in high dose and control animals).

Clinical pathology Haematology (pre-exposure, wk 4 and wk 12): haematocrit, haemoglobin, erythrocyte count, mean cell volume, mean cell haemoglobin concentration, total and differential leucocyte count prothrombin time and partial thromboplastin time.

Biochemistry (pre-exposure, wk 4 and wk 12) blood urea nitrogen, glucose, alkaline phosphatase, glutamate pyruvate transaminase, glutamate oxaloacetate transaminase, total protein and

albumin/globulin, sodium and potassium.

Urinalysis (pre-exposure, wk 4 and wk 12): samples were collected overnight to measure following parameters: volume, appearance and colour, specific gravity, pH, glucose, protein, ketones, bilirubin, blood pigments and deposit.

Necropsy

Gross examination;

Macroscopy of cranial, thoracic and visceral cavities;

Organ weights of brain, kidneys, liver, adrenals, heart, lungs, ovaries, pituitary, spleen, testes, thyroids and uterus;

Microscopy of following organs for animals in the high dose and control group: adrenals, aortic arch, brain, caecum, cervical lymph nodes, colon, duodenum, epididymes, eyes, heart, ileum, jejunum, kidneys, liver, lungs, caudal and cranial mammary gland, mesenteric lymph nodes, optic nerve, ovaries, pancreas, pituitary, prostate, spleen, stomach, testes, thymus, thyroids, urinary bladder and uterus. Stomachs of middle and low dose animals were also examined.

Analysis Concentration analysis on day 1 by comparing absorbances with those of standard solutions.

Results

Dose	0 mg/kg		75 mg/kg		250 mg/kg		750 mg/kg		Dose related	
Sex	M	F	M	F	M	F	M	F	M	F
Mortality	No test substance related deaths occurred*									
Clinical Signs (A)					+	+	+	+		
Body weight gain	No treatment related changes.									
Food consumption	No treatment related changes.									
Ophthalmoscopy	No treatment related changes.									
Haematology										
WBC, wk 4 (wk 12)**							dc (d)			
Clinical chemistry	No changes of toxicological significance.									
BUN, wk 4 (wk12)**				(ic)		lc (ic)		lc (ic)		
Urinalysis										
Urinary volume (B)								i		
Specific gravity								d		
Necropsy	No test substance related abnormalities.									
Macroscopy										
Liver weight								ic ^{a,r}		
Microscopy (C)					+	+	+	+	x	x

Where i=increase; d=decrease; ic=significant increase; dc=significant decrease; ^a=absolute; ^r=relative.

*One control female died during blood sampling.

**The changes were not of toxicological significance.

(C) Post dose salivation from week 3 (750 mg/kg) of week 8 (250 mg/kg) on.

(D) Increased volume after both 4 and 12 weeks, reduced specific gravity after 12 weeks.

(E) Changes were restricted to the stomach and consisted of hyperplasia of the non-glandular squamous epithelium, with associated focal epithelial erosion and varying degrees of gastritis in some rats. In females at high dose, epithelial whorls were seen in the thyroid.

Actual concentrations Concentrations as measured were 99% of nominal concentrations.

Conclusions NOAEL = 75 mg/kg/day and LOAEL = 250 mg/kg/day, as based on histological changes in stomach mucosa in both sexes.

Rev. note Study is in accordance with the old OECD guideline 408 (1981). The new guideline requires a more extensive biochemical and histological examination, recording of more organ weights and measurement of sensory reactivity.

Klimisch criterium 1